

PART 80—COLOR ADDITIVE CERTIFICATION

Subpart A—General Provisions

Sec.

80.10 Fees for certification services.

Subpart B—Certification Procedures

80.21 Request for certification.

80.22 Samples to accompany requests for certification.

80.31 Certification.

80.32 Limitations of certificates.

80.34 Authority to refuse certification service.

80.35 Color additive mixtures; certification and exemption from certification.

80.37 Treatment of batch pending certification.

80.38 Treatment of batch after certification.

80.39 Records of distribution.

AUTHORITY: 21 U.S.C. 371, 379e.

SOURCE: 42 FR 15662, Mar. 22, 1977, unless otherwise noted.

Subpart A—General Provisions

§ 80.10 Fees for certification services.

(a) *Fees for straight colors including lakes.* The fee for the services provided by the regulations in this part in the case of each request for certification submitted in accordance with § 80.21(j)(1) and (j)(2) shall be 30 cents per pound of the batch covered by such requests, but no such fee shall be less than \$192.

(b) *Fees for repacks of certified color additives and color additive mixtures.* The fees for the services provided under the regulations in this part in the case of each request for certification submitted in accordance with § 80.21(j)(3) and (j)(4) shall be:

(1) 100 pounds or less—\$30.

(2) Over 100 pounds but not over 1,000 pounds—\$30 plus 6 cents for each pound over 100 pounds.

(3) Over 1,000 pounds—\$84 plus 2 cents for each pound over 1,000 pounds.

(c) *Advance deposits.* Any person regularly requesting certification services may deposit funds in advance of requests as prepayment of fees required by this section.

(d) *Method of payment.* All deposits and fees required by this section shall be paid by money order, bank draft, or certified check, drawn to the order of

the Food and Drug Administration, collectable at par at Washington, DC. All such deposits and fees shall be forwarded to the Center for Food Safety and Applied Nutrition (HFS-100), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, whereupon after making appropriate records thereof, they will be transmitted to the Treasurer of the United States for deposit to the special account “Salaries and Expenses, Certification, Inspection, and Other Services, Food and Drug Administration.”

(e) *Refunds from advance deposits.* Whenever in the judgment of the Commissioner the ratio between fees collected (which are based upon experience and the best estimate of costs and the best estimate of earnings) and the costs of providing the service during an elapsed period of time, in the light of all circumstances and contingencies, warrants a refund from the fund collected during such period, he shall make ratable refunds to those persons to whom the services were rendered and charged, except that no refund shall be made where the computed ratable amount for the elapsed period is less than \$5.00.

[42 FR 15662, Mar. 22, 1977, as amended at 47 FR 24692, June 8, 1982; 54 FR 24890, June 12, 1989; 59 FR 60899, Nov. 29, 1994; 61 FR 3572, Feb. 1, 1996; 61 FR 14479, Apr. 2, 1996; 66 FR 56035, Nov. 6, 2001]

EFFECTIVE DATE NOTE: At 70 FR 15756, Mar. 29, 2005, § 80.10 was amended by revising paragraphs (a) and (b), effective Apr. 28, 2005. For the convenience of the user, the revised text is set forth as follows:

§ 80.10 Fees for certification services.

(a) *Fees for straight colors including lakes.* The fee for the services provided by the regulations in this part in the case of each request for certification submitted in accordance with § 80.21(j)(1) and (j)(2) shall be \$0.35 per pound of the batch covered by such requests, but no such fee shall be less than \$224.

(b) *Fees for repacks of certified color additives and color additive mixtures.* The fees for the services provided under the regulations in this part in the case of each request for certification submitted in accordance with § 80.21(j)(3) and (j)(4) shall be:

(1) 100 pounds or less—\$35.

(2) Over 100 pounds but not over 1,000 pounds—\$35 plus \$0.05 for each pound over 100 pounds.

§ 80.21

21 CFR Ch. I (4–1–05 Edition)

(3) Over 1,000 pounds—\$89 plus \$0.02 for each pound over 1,000 pounds.

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Subpart B—Certification Procedures

§ 80.21 Request for certification.

A request for certification of a batch of color additive shall:

(a) Be addressed to the Commissioner of Food and Drugs.

(b) Be prepared in the manner set forth in paragraph (j) of this section.

(c) Be submitted in duplicate.

(d) Be signed by a responsible officer of the person requesting certification of the batch. In the case of a foreign manufacturer, the request for certification must be signed by a responsible officer of such firm, and, by his agent who resides in the United States.

(e) Show the name and post office address of the actual manufacturer in case such manufacturer is not the person requesting certification of the batch.

(f) Be accompanied by the fee prescribed in § 80.10 unless the person has established with the Food and Drug Administration an advanced deposit to be used for prepayment of such fees. In no case shall the Commissioner consider a request for certification of a batch of color additive if the fee accompanying such request is less than that required by § 80.10 or if such fee exceeds the amount held in the advance deposit account of the manufacturer submitting such request for certification.

(g) Be accompanied by the sample prescribed in § 80.22 consisting of:

(1) Four ounces in the case of straight colors and lakes.

(2) Two ounces in the case of repacks and mixtures.

A sample accompanying a request for certification must be submitted under separate cover and should be addressed to the Color Certification Branch.

(h) The name of a color additive shall be given in the following manner:

(1) The name of a straight color shall be the name of the color as listed in parts 74 and 81 of this chapter.

(2) The name of a lake shall be the name derived in the manner described in part 82 of this chapter.

(3) The name of a mixture shall be the name given to such mixture by the person requesting certification.

(4) The name of a repack shall be the name described in paragraph (h)(1), (2), or (3) of this section, whichever is applicable.

(i) The information and samples enumerated in paragraphs (a) to (h), inclusive, of this section are the minimum required. Additional information and samples shall be submitted at the request of the Food and Drug Administration when such additional information and samples are necessary to determine compliance with the requirements of § 80.31 for the issuance of a certificate.

(j) The form for submission of the application shall be one of the following, depending upon whether the color additive is a straight color, a lake, a repack of a previously certified color additive, or a color additive mixture.

(1) *Request for certification of a batch of straight color additive.*

Date _____
Office of Cosmetics and Colors (HFS-100),
Center for Food Safety and Applied Nutrition,
Food and Drug Administration,
5100 Paint Branch Pkwy.,
College Park, MD 20740

In accordance with the regulations promulgated under the Federal Food, Drug, and Cosmetic Act, we hereby make application for the certification of a batch of straight color additive.

Name of color _____
(As listed in 21 CFR part 74)

Batch number _____
(Manufacturer's number)

Batch weighs _____ pounds
Batch manufactured by _____ at
_____ (Name and address of actual manufacturer)

How stored pending certification _____

(State conditions of storage, with kind and size of containers, location, etc.)

Certification requested of this color for use in _____

(State proposed uses)

Required fee, \$ _____ (drawn to the order of Food and Drug Administration).